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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/691,846 | 10/23/2003 | Donald K. Jones | CRD5035CIP1 | 6702 |
| 27777 | 7590 | 04/20/2004 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | WEBB, SARAH K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,846

Applicant(s)

JONES ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/19/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 10 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,873,907 to Frantzen.

Frantzen discloses a self-expanding stent and delivery system. In Figures 1A and 1B, Frantzen illustrates a stent (10) that is a tubular member with a plurality of cells in the outer surface wall formed by a plurality of strut members. Frantzen explains that the stent is made from a nickel-titanium alloy (column 3, line 22), which is self-expanding. Figure 3A shows the stent (10) mounted on an elongated core member (21). Frantzen explains that a retractable exterior sheath, or slidable catheter, may be used to deploy the stent and core member (column 7, line 10). Three retaining rings (30) are disposed around the stent (10) for constraining the stent in its contracted diameter (column 3, lines 34-36). The retaining rings (30) disintegrate when exposed to an electric current (column 4, line 26).

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2. Claims 10-12 and 16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,607,539 to Hayashi et al.

Hayashi discloses a self-expanding vascular graft, or stent, delivery system in Figures 4, 5A, 5B that includes an elongated core (20) member, a self-expanding graft (15), and actuatable retaining rings (127) disposed around the graft (15). In lines 17-20 of column 3, Hayashi explains that a conventional catheter may be used with the delivery system, where the core member (20) and graft (15) would be slidably disposed within its lumen. Electrical conductors (25,26) are connected to resistive heating elements (129,130) that are positioned near the retaining rings (127). In lines 45-53 of column 3, Hayashi explains that the retaining rings (127) are severed by heat supplied by the resistive heating elements (129,130) to allow the self-expanding graft (15) to expand. Figure 5B clearly illustrates the severed retaining rings (127).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. in view of U.S. Patent No. 6, 277,126 to Barry et al.

Hayashi includes all the limitations of claims 13 –15 except for the retaining ring comprising a polymeric fiber or hot melt polymer. Hayashi does state that the retaining rings should be made from suture material (column 4, line 26), which includes many

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types of polymer filaments. Barry discloses another type of delivery system, in which an electric current is supplied to a resistive heating element. The heat is used to sever a coupling, thereby releasing a vascular implant. Here, Barry teaches that the coupling material can be a hot melt adhesive (which is inherently a polymer), because this type of material softens and yields when exposed to heat. (See column 4, lines 29 – 40.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the retaining filaments of Hayashi from a hot melt polymeric material, as taught by Barry, as this material is suitable for forming retaining elements that yield with the application of heat in a vascular implant delivery system.

Regarding claim 15, Hayashi states throughout the document that the heating elements (129,130) are resistive.

4. Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. in view of U.S. Patent No. 5,919,225 to Lau et al. and in further view of U.S. Patent No. 6,165,213 to Goicoechea et al.

As explained above, Hayashi includes many features of the claimed invention, except for some of the limitations in claim 1. Hayashi does explain that the graft, or stent, may be woven (column 4, line 35). A woven structure inherently comprises a plurality of cells formed by a plurality of strut members.

Hayashi lacks proximal and distal cylindrical members disposed on the core member. Lau et al. discloses a stent delivery system in Figures 19A-C that includes a core member (318) with both proximal and distal cylindrical members (322 and 320) attached to the core member (318). Lau teaches that the cylindrical members (320,322)

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hold the stent (312) axially in place on the core member (318) prior to deployment (column 18, lines 16-19). The gap defined between the members (320,322) is at least as long as the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include proximal and distal cylindrical members on the core member of Hayashi, as taught by Lau, as this provides barriers that hold the graft, or stent, axially in place relative to the core member prior to deployment.

Hayashi also lacks an anchor member on one of the struts. Goicoechea discloses a stent that has a plurality of cells formed by a plurality of struts. As shown in Figure 4a, Goicoechea shows that a radiopaque marker, or "anchor", can be in the form of wire wrapped around a strut (17). Goicoechea teaches that the radiopaque marker allows the delivery of the stent to be monitored using x-rays (column 10, lines 51-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a radiopaque marker, or "anchor", on one of the struts of Hayashi, as Goicoechea teaches that this allows the stent to be monitored during delivery.

Regarding claims 2 and 3, Figure 4 of Hayashi clearly illustrates that the system includes a proximal retaining ring and a distal retaining ring. Claims 4, 5, and 9 were discussed above.

5. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Lau and Goicoechea, as applied to claim 5 above, and further in view of Barry.

Hayashi, as modified by Lau and Goicoechea above, includes all the limitations of claims 6-8 except for the retaining ring being a hot melt polymer filament. Hayashi

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does state that the retaining rings should be made from suture material (column 4, line 26), which includes many types of polymer filaments. Barry discloses another type of delivery system, in which an electric current is supplied to a resistive heating element. The heat is used to sever a coupling, thereby releasing a vascular implant. Here, Barry teaches that the coupling material can be a hot melt adhesive (which is inherently a polymer), because this type of material softens and yields when exposed to heat. (See column 4, lines 29 – 40.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the retaining filaments of Hayashi from a hot melt polymeric material, as taught by Barry, as this material is suitable for forming retaining elements that yield with the application of heat in a vascular implant delivery system.

Conclusion


6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,350,277 to Kocur discloses a stent with a retaining band. US 6,514,285 to Pinchasik discloses a stent with retaining members that are severed by heat supplied by electric current.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW


MICHAEL J. MILANO 4/15/04
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